

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

COLLAGENEX PHARMACEUTICALS, INC.,

Plaintiff,
v.
MUTUAL PHARMACEUTICAL COMPANY, INC. and
UNITED RESEARCH LABORATORIES, INC.,
Defendants.

CV 03 3322

) COMPLAINT AND
JURY DEMAND

) ROSS, J.

FILED

IN CLERK'S OFFICE
U.S. DISTRICT COURT, E.D.N.Y.

★ JUL - 8 2003 ★

BROOKLYN OFFICE

MANN, M.J.

COMPLAINT

Plaintiff, CollaGenex Pharmaceuticals, Inc. ("CollaGenex"), for its Complaint against Defendant, Mutual Pharmaceutical Company, Inc. ("Mutual") and United Research Laboratories, Inc. ("United"), alleges as follows:

THE PARTIES

1. CollaGenex is a publicly traded corporation organized under the laws of the state of Delaware and having a principal place of business at 41 University Drive, Newtown, Pennsylvania 18940.
2. On information and belief, Mutual is a corporation organized under the laws of the state of Pennsylvania, and having a principal place of business at 1100 Orthodox Street, Philadelphia, PA 19124.

3. On information and belief, United is a corporation organized under the laws of the state of Pennsylvania, and having a principal place of business at 1100 Orthodox Street, Philadelphia, PA 19124.

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction of this action pursuant to 28 U.S.C. §1331 and 1338(a) and (b), and has supplemental jurisdiction over CollaGenex's state law under 28 U.S.C. §1337.

5. This Court is empowered to provide declaratory judgment as a remedy in this action pursuant to 28 U.S.C. §2201 and §2202.

6. On information and belief, Mutual has contacts with New York as follows:

i) Does business in New York generally;

ii) Employs and/or engages agents and/or representatives in New York to perform services on its behalf;

iii) Has substantial sales of pharmaceutical products in New York; and

iv) Advertises in trade journals or other written and/or printed materials in hard copy and/or electronically directed to residents and companies in the state of New York.

7. On information and belief, United has contacts with New York as follows:
 - i) Does business in New York generally;
 - ii) Employs and/or engages agents and/or representatives in New York to perform services on its behalf;
 - iii) Has substantial sales of pharmaceutical products in New York; and
 - iv) Advertises in trade journals or other written and/or printed materials in hard-copy and/or electronically directed to residents and companies in the state of New York.
8. Thus, on information and belief, Mutual either separately or in cooperation with other companies and/or its agents has a presence in the state of New York amounting to a continuous course of conduct in New York such that of assertion of *in personam* jurisdiction over Mutual comports with the requirements of due process and notions of fairness.
9. Thus, on information and belief, United either separately or in cooperation with other companies and/or its agents has a presence in the state of New York amounting to a continuous course of conduct in New York such that of assertion of *in personam* jurisdiction over United comports with the requirements of due process and notions of fairness.
10. Venue is proper in this district pursuant to 28 U.S.C. §1391(b), §1391(c) and §1400(b).

COLLAGENEX PHARMACEUTICALS, INC.

11. CollaGenex is a specialty pharmaceutical company which provides innovative medical therapies for targeted disease classes. CollaGenex currently services the dental and dermatology markets. CollaGenex' flagship product is Periostat®, an oral enzyme suppressing-agent and bone protein-enhancing agent. Periostat® provides the first and only systemic pharmaceutical treatment for adult periodontitis, which works by: i) inhibiting the enzymes which destroy periodontal support tissue(s) and ii) enhancing bone protein synthesis.
12. CollaGenex is a publicly traded company which is primarily based on a core technology originating from research conducted at the laboratories of the State University of New York at Stony Brook by Dr. Lorne M. Golub. Dr. Golub, et al. discovered certain unique properties of tetracycline compounds, such properties being the subject of a series of U.S. patents (assigned to the Research Foundation of the State University of New York) which are exclusively licensed to CollaGenex.
13. Over the years, CollaGenex has invested over 20 million dollars in the development of Periostat® as an FDA (Food and Drug Administration)-approved, ADA (American Dental Association)-accepted, prescription drug for use in the treatment of adult periodontitis, and has actively engaged in marketing and sales of Periostat® throughout the world.

14. Periostat® is CollaGenex' primary product, and its (i) commercial reputation, (ii) maintenance of primary income stream, and (iii) value of the company reside in sustaining the premier market position of Periostat®.

PERIOSTAT®

15. Periostat® works by reducing the activity of the enzymes which destroy tooth and gum tissue and by enhancing bone protein synthesis.

16. Periostat® also works by enhancing bone protein synthesis, and has been shown to reduce pocket depth and promote attachment level gain in patients suffering from adult periodontitis.

17. Periostat® is available only by prescription from a dentist or periodontist or physician.

18. Periostat® is a tablet containing 20mg of doxycycline hyclate. This tablet is administered twice a day by the patient. Extensive research conducted by Dr. Golub and CollaGenex established that this dose and dosage regimen delivers a sub anti-microbial dosage of the active ingredient doxycycline hyclate, which unexpectedly, is both safe and effective for long term administration to patients. Periostat® differs fundamentally from other formulations of tetracycline and its derivatives in that it is a tetracycline compound and dosage form proven safe for long term administration; and, as demonstrated through extensive clinical trials, does not affect the numbers of resident microflora of the body and does not contribute to the development of antimicrobial resistance.

19. On the basis of these trials, CollaGenex obtained approval for Periostat® from the FDA for the treatment of adult periodontitis.

PATENTS COVERING PERIOSTAT®

20. The use of the Periostat® product for the treatment of adult periodontitis, is covered by U.S. Patent No. 4,666,897 (Exhibit A) and Re-Issue Patent RE 34,656 (Exhibit B) referred to herein collectively as the "patents in suit." The '897 patent does not expire until May 19, 2004; and the RE 34,656 patent does not expire until May 15, 2007. Both patents in suit are printed on the package insert for Periostat® whereby notice under 35 U.S.C. § 287 is provided.
21. Both of these patents have been issued to Dr. Golub, et al. and have been assigned to The Research Foundation of the State University of New York.
22. These patents and other patents relating to Dr. Golub's technology are exclusively licensed to CollaGenex. Under the license from The Research Foundation CollaGenex has the authority to enforce the rights provided by the patents in suit.

THE INFRINGERS

23. On information and belief, United is a generic drug company which provides to the marketplace generic drugs.
24. On information and belief, Mutual is United's manufacturing arm, which manufactures the generic drugs.

25. On information and belief, Mutual and United are wholly owned subsidiaries of Pharmaceutical Holdings Corp.
26. On information and belief, United and Mutual conduct business under the name "URL Mutual."
27. On information and belief, generic drugs that United and/or Mutual provide to the commercial marketplace are shown at Exhibit C, which lists at least 600 generic drug products.

INFRINGEMENT UNDER 35 U.S.C. § 271(e)(2)(A)

28. The patents in suit cover the use of Periostat® to treat patients with adult periodontitis.
29. Specifically, the two patents cover the treatment of patients by use of Periostat® since it reduces a pathological excess of collagenolytic enzyme activity in patients infected thereof and since it enhances bone protein synthesis in patients with bone deficiency disorders, such as periodontitis.
30. On information and belief, Mutual has submitted an abbreviated new drug application ("ANDA") under § 505(j) of the Federal Food, Drug, and Cosmetic Act for doxycycline hyclate tablets, 20mg, based on the fact that the Mutual drug and its use are the same as the Periostat® drug and its use.

31. Therefore, Mutual has committed an act of infringement and continues to infringe under 35 U.S.C. § 271(e)(2)(A) which states as follows:

"§ 271...

... (e) ...

(2) It shall be an act of infringement to submit—

(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act...for a drug claimed in a patent or the use of which is claimed in a patent,

...

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent. ”

32. On information and belief, Mutual willfully and wantonly submitted the ANDA for generic Periostat® with full knowledge of the patents in suit and in complete disregard of CollaGenex's legitimate patent rights.

33. Thus, Mutual has engaged in infringing activity under 35 U.S.C. § 271(e)(2)(A), with full knowledge of the patents in suit.

34. In accordance with 35 U.S.C. § 271(e)(4)(A) CollaGenex is entitled to an order from the Court requiring the date of approval of Mutual's generic form of Periostat® be no earlier than the date of the last to expire of patents in suit, i.e., May 15, 2007.

35. Further, in accordance with 35 U.S.C. § 271(e)(4)(B), CollaGenex is entitled to injunctive relief against Mutual to prevent the commercial manufacture, use, offer to sell, and sale within the United States and importation into United States of a generic form of Periostat® in accordance with its label and package insert.

INFRINGEMENT UNDER 35 U.S.C. § 271(b) OR § 271(c)

36. Under § 505(j) of the Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j), the FDA will approve Mutual's ANDA if Mutual has shown, *inter alia*, that the active ingredient in its tablet is the same as the active ingredient in the Periostat® tablets and is bioequivalent, and the labeling (package insert) is the same as the labeling for Periostat® tablets. On information and belief, Mutual's ANDA states that it has fulfilled these requirements.

37. Since the patents in suit cover methods of treating patients, which are infringed when following the treatment described in the package insert, infringement of the patents in suit also occurs under 35 U.S.C. §271(b) and/or 35 U.S.C. §271(c) based on unauthorized (i.e., unlicensed) sale and offer for sale of a generic form of Periostat® for the same treatment as Periostat®.

38. Mutual has solicited the State Formulary of New Jersey to list it as a source for generic replacement for Periostat®. See Exhibit D. Mutual's listing on the formulary for the State of New Jersey for a generic replacement for Periostat® will induce sales and use of the generic replacement, and will contribute to direct infringement by the user of the drug, i.e., the patient.

39. Mutual has indicated that it intends to market and sell generic Periostat® upon approval of its ANDA. See Exhibit E. Mutual's attorneys have threatened that, if CollaGenex attempts to enforce its patents related to Periostat®, or if CollaGenex interferes with Mutual's FDA approval process or its marketing efforts for doxycycline hyclate 20 mg tablets, Mutual will refer the matter to the FTC for investigation.
40. Moreover, United has already, prior to receiving FDA approval, made offers to sell generic Periostat® and to ship the generic Periostat® in the United States immediately upon receiving FDA approval. See Exhibit F.
41. By advising and otherwise promoting its 20 mg doxycycline hycalate tablets as "generic Periostat®," United and Mutual are trading on and/or invoking the marketing, good will and product claims of CollaGenex, established through CollaGenex's own marketing, sales and training of the profession (e.g., periodontists).
42. United's and Mutual's offer for sale, sale and/or marketing of their drug as generic Periostat®, in accordance with CollaGenex's marketing and labeling of Periostat®, induces others to infringe CollaGenex's patent claims and renders United and Mutual liable as inducers for inducement under 35 U.S.C. §271(b) and/or for contributory infringement under 35 U.S.C. §271(c).
43. The aforementioned actions of United and Mutual, including submitting the ANDA and marketing and offering for sale generic Periostat®, were taken willfully and wantonly in complete disregard of CollaGenex's legitimate patent rights.

44. Consequently, CollaGenex is entitled to injunctive relief under 35 U.S.C. §283 from Mutual's and United's infringing activity.
45. Furthermore, CollaGenex is entitled to damages under 35 U.S.C. §284 resulting from Mutual's and United's infringing activities, including treble damages and attorneys fees under 35 U.S.C. §285 as the Court may find.

UNFAIR COMPETITION

46. CollaGenex incorporates by reference the allegations of paragraphs 1 through 45.
47. On information and belief, United has sent letters to drug distributors in the United States, soliciting sales of generic Periostat®, prior to receiving FDA approval. See Exhibit F.
48. These letters advise that "we [United] are requesting you [distributor] to pre-book your order [for generic Periostat®] so that URL [United] will be able to ship product to you upon receipt of FDA approval."
49. Since use of generic Periostat® by patients will infringe the patents in suit, sales by United of generic Periostat® during the term of the patents will be inducing or contributing to such infringement.
50. Thus, United is misrepresenting, and misleading distributors into believing, that it is permitted to sell generic Periostat® despite CollaGenex's valid patents. Moreover,

United is misleading distributors into believing that it is permissible for generic Periostat® to be sold to and used by patients.

51. Therefore, United's solicitation letters contain false and misleading statements, misrepresentations of fact, and constitute unfair competition in violation of 15 U.S.C. § 12(a), the laws of the states of New York, Pennsylvania and Hawaii, and those states who have adopted the Uniform Deceptive Trade Practices Act.

TORTIOUS INTERFERENCE

52. CollaGenex incorporates by reference the allegations of paragraphs 1 through 51.
53. On information and belief, United's solicitation letters have been sent to distributors that have business relationships with CollaGenex.
54. On information and belief, United's solicitation letters were also sent to distributors with which CollaGenex was attempting to establish a business relationship.
55. On information and belief, based upon the false and misleading statements in the solicitation letters, United has interfered with and/or disrupted CollaGenex's business relationships or prospective business relationships with distributors.
56. On information and belief, CollaGenex has lost sales and or orders for Periostat® as a result of United's actions in improperly soliciting distributors.

57. Therefore, by sending the solicitation letters to such distributors, United has tortiously interfered with CollaGenex existing business relationships and prospective business relationships.

INJURY

58. Mutual and United are poised to introduce product into the commercial marketplace which, in use, will infringe the CollaGenex patents and which will have irrevocable impact on the reputation, product and sales, and the very viability of CollaGenex as a company.

59. Unless enjoined by this Court, Mutual and United intend to, and will continue a course of conduct which will, infringe the patents in suit. As a direct and proximate result of the acts of Mutual and United, CollaGenex will suffer irreparable harm and sustain untold loss of revenue, reputation, and stock value. CollaGenex has no adequate remedy at law to redress such injuries that Mutual and United intend to cause and will cause by their conduct.

60. Further, as direct result of Mutual and United having already offered generic PerioStat® for sale, CollaGenex has been injured to the extent it has lost orders and sales for PerioStat®.

61. Moreover, Mutual and United have already caused damage to CollaGenex through its false and misleading statements to distributors, including distributors which CollaGenex has existing business relationships.

62. CollaGenex is entitled to a preliminary and permanent injunction restraining Mutual and United, their officers, agents, employees, and all persons acting in concert with Mutual or United, from engaging in any further acts related to the infringement of the patents in suit; and to damages and attorney fees as set forth in the statute.

PRAYER FOR RELIEF

WHEREFORE, CollaGenex prays for an order:

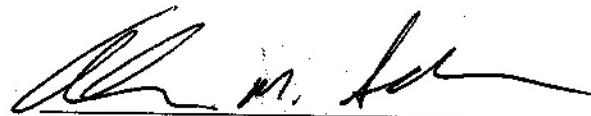
- a. Making the effective date of any approval of the generic form of Periostat® by the FDA be not earlier than the date of expiration of the last to expire of the patents in suit; i.e., not earlier than May 15, 2007;
- b. Imposing injunctive relief against Mutual and United to prevent the commercial manufacture, use, offer to sell, and sale within the United States and importation into the United States of a generic form of Periostat® in the manner prescribed on the label and package insert;
- c. Declaring that Mutual and United will infringe U.S. Patent No. 4,666,897 and U.S. Patent RE 34,656 under 35 U.S.C. §271(b) and §271(c), by introducing the generic form of Periostat® to the marketplace upon FDA approval of the generic form of Periostat®;
- d. Declaring that any of the acts of sales, offer for sale, and importation into the United States of a generic form of Periostat® for the prescribed use will infringe U.S. Patent No. 4,666,897 and U.S. Patent RE 34,656;

- e. Preliminarily and permanently enjoining Mutual and United, their officers, agents, servants, employees and attorneys and all those persons acting in concert or participation with Mutual and United from infringing the patents in suit;
- f. Preliminarily and permanently enjoining Mutual and United, their officers, agents, servants, employees and attorneys and all those persons acting in concert or participation with Mutual and United from marketing or offering for sale generic Periostat® in the manner prescribed on the label and package insert;
- g. Finding Mutual and United liable as infringers for inducement under 35 U.S.C. § 271(b), based on the offer for sale of generic Periostat®.
- h. Awarding to CollaGenex any damages incurred by acts undertaken by Mutual and United for infringement of the patents in suit, unfair competition and tortious interference with CollaGenex's business relationships, including damages for lost orders and sales, corrective advertising and attorneys fees;
- i. Requiring Mutual and United to take all actions necessary to prevent introduction of infringing product into commerce in the United States, to issue corrective advertising and to identify all orders placed for generic Periostat® in sufficient detail to permit CollaGenex to conduct an accounting of damages;

- j. Awarding to CollaGenex as against Mutual and United aggravated damages up to three times the amount assessed and the cost of the suit, including attorneys fees; and
- k. Such other further relief as the Court deems just.

This the 8th day of Jul, 2003.

Respectfully submitted,

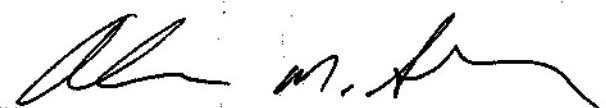


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JURY DEMAND

CollaGenex hereby demands a trial by jury on all issues triable to jury.

Respectfully submitted,



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